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March 14, 2024

**VIA ECF**

Honorable Edward S. Kiel, U.S.M.J.  
United States District Court, District of New Jersey  
United States Post Office & Courthouse  
Federal Square, Courtroom 8  
Newark, New Jersey, 07101

**Re:    *United States ex rel. Silbersher v. Janssen Biotech Inc., et al.***  
**Civil Action No. 19-12107 (MEF-ESK)**

Dear Judge Kiel:

The parties submit this letter in the above-captioned matter pursuant to Civil Local Rule 37.1 governing discovery disputes and the Court's Case Management Order. The parties met and conferred on the issues raised in this letter during multiple meet and confers over the past several weeks, and most recently on February 26, 2024. The parties were unable to reach a resolution, and therefore are at an impasse.

**I.    Relator's Statement**

**A.    Relator's Document Request Nos. 68-87: Targeted Keyword Searches.**

Relator respectfully requests that this Court direct Defendants to produce documents responsive to Request Nos. 68 through 87 (served on January 19, 2024) seeking documents in 17 key witnesses' custodial files (two have been withdrawn, Nos. 70 and 71), including those of Andrea Kamage, Timothy Tracy, and Paul Short. Ms. Kamage was Johnsson & Johnson's lead patent prosecuting attorney up to the filing of the critical June 4, 2013 submission concerning

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commercial success. Mr. Tracy took over the lead for patent prosecution and filed several “Information Disclosure Statements” after the June 2013 submission and before the September 2014 issuance of the ’438 Patent that Relator claims was fraudulently obtained. And Mr. Short was the lead manager that appears to have been most responsible for crafting Defendants’ commercial strategy for Zytiga. The other witnesses are important witnesses (out of potentially scores of witnesses) that Relator has identified as possessing important information relating to Defendants’ knowledge of the real reasons for Zytiga’s commercial success—which is one of the central issues in this case.

Relator seeks documents in the files of key witnesses identified through review of Defendants’ document production, a production that Defendants have dribbled out over a period of years, including as recently as January and February 2024. The reason Relator chose these terms is because certain key documents that are expected to be critical at trial were apparently widely disseminated through the company, but the metadata for those documents do not indicate the recipients. Because knowledge of key facts for certain witnesses is important, Relator must be permitted the opportunity to confirm whether certain key documents reside within the custodial files of important witnesses to establish those witnesses’ knowledge of those facts. This discovery is focused and targeted to the most important issues in this case and should be produced by Defendants.

The terms that Relator has identified as important (based on the titles of key documents, such as SWOT or “Strengths, Weaknesses, Opportunities, and Threats” assessments for Zytiga, as

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well as important patterns of words and phrases that recur in their contents) include:<sup>1</sup>

1. SWOT & (abiraterone Zytiga AA)

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<sup>1</sup> The document requests are addressed to the following witnesses: (1) **Patent prosecution attorneys**: Andrea Kamage and Timothy Tracy; (2) **Senior J&J commercial and marketing personnel** who participated in the recently disclosed (*i.e.*, January and February 2024) **Zytiga Compound Development Team** and **Clinical Team**, as well as the **Global Commercial Team**, all of whom apparently discussed the drivers for Zytiga's commercial success with J&J's patent prosecution attorneys: Paul Short; Michael Meyers; Louis Langas; William Daly; Arturo Molina; Stan Panasewicz; Craig Tendler; Mary Todd; Suneel Mundle, and Victoria Vakiener; (3) **other senior executives and managers** whom Relator believes possess important information, based on Defendants' interrogatory responses, Rule 26 disclosures, and Relator's review of the documents: Dimitry Gitarts, Robert Bazemore, Joquin Duato, Frank Dooley, Myra MacCormack, and Alex Gorsky. Categories (1) and (2) are of the highest priority. There were two other witnesses who Defendants identified as having relevant knowledge of the patent prosecution (two paralegals, but after taking their depositions, Relator withdraws those requests (Nos. 70 & 71).

Each of the document requests begin with a general description of the category to which the requested documents are expected to relate requested, restricted by a terms and connectors search that narrows the requested documents to a specific subset. Each of the full requests begin with "Documents within the custodial files of [the witness] that discuss or analyze Zytiga against any actual or potential competitors, including, without limitation, any factors bearing on the commercial success of Zytiga as described in Paragraphs 84 and 87 of the Second Amended Complaint, or the reasons Zytiga would have to be administered with prednisone or other glucocorticoid, **such that any of the following terms** are contained within the document as provided in Instruction No. 19, *supra*." (Emphasis added.)

According to Instruction No. 19, the term searches employ common Boolean commands. For example, spaces between terms denote "or" such that the presence of any one of the grouped terms separated by spaces would identify a responsive document within a specified category of documents. An ampersand ("&") between terms denotes "and" such that the connected terms must appear within a responsive document for the document to be responsive to a specified category. A slash followed by a "p" (*i.e.*, "/p") between terms means that the connected terms must appear within the same page anywhere in the document for the document to be responsive to a specified category. A slash followed by a "s" (*i.e.*, "/s") between terms means that the connected terms must appear within the same sentence anywhere in the document for the document to be responsive to a specified category. An exclamation mark is a root expander.

Terms appearing within parentheses means that the foregoing instructions are applied first to the terms within the parentheses. In applying this rule, the terms within parentheses are then collectively considered a "term" for the purposes of applying the foregoing instructions.

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2. S.W.O.T. & (abiraterone Zytiga AA)
3. (prednisone) /p (strength weak! obstacle!)
4. (abiraterone Zytiga AA) /p (strength weak! obstacle!)
5. (abiraterone Zytiga AA) & (MDV xtandi enzalutamide)
6. (abiraterone Zytiga AA) & (strategic /s (insight analysis plan))
7. (sequenc!) & (abiraterone Zytiga)
8. (obstacle weakness tailwind) & (abiraterone Zytiga)
9. Zytiga & (business /s plan)
10. Zytiga & (key /s assets)
11. (NALT (North /s American /s Leadership /s Team)) & Zytiga
12. (President! /s Review) & Zytiga
13. (LRFP (Long /s Range /s Financial /s Plan!)) & Zytiga
14. (LRFP (Long /s Range /s Financial /s Plan!)) & Zytiga
15. (Proposal /s (GOc (Group /s Operation! /s Committee)) & Zytiga
16. (Landscape /s Assessment) & Zytiga
17. Zytiga & (Strategic /s Plan)
18. Zytiga & (Overview)
19. Zytiga & (Key /s Asset)
20. Zytiga & (Regional /s Update)

Defendants advance three arguments resisting this production. *First*, Defendants say that these requests are duplicative of prior document requests. They are not. Defendants' prior

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productions have revealed critical, strategic planning documents that Relator believes demonstrate Defendants' knowledge that the Commercial Success statements they made to the Patent Office were false. For example, there are certain "Long Range Financial Planning" documents, "Landscape Assessment" Reports, "NALT [North American Leadership Team] Reports," SWOT Analyses, "Regional Updates," and "Annual Business Plans," "President's Review," and "Key Assets" reports, among others, that Relator has been able to identify only *after* searching and reviewing the millions of pages of documents Defendants have produced in this case. The most important of these documents were not produced until Defendants' later productions scattered throughout 2023 and even 2024—as is evident by their Bates numbers. Defendants obviously saved the best for last—as most of these critical documents were produced only after Defendants had buried them behind approximately 5.5 million pages of earlier productions.

Accordingly, Requests 68-87 (except 70 & 71, which are withdrawn): (a) focus on the most important documents that Relator has identified and (b) seek to tie them to key witnesses. This was possible only after analyzing Defendants' prior productions, including key documents that Defendants claim to have only recently found and belatedly produced (in January and February 2024), which disclose the existence, membership, agendas, and minutes, of Zytiga's Compound Development Team and Clinical Team.

Relator's request is also necessary because Defendants did not preserve all the recipients and custodians in the metadata when they produced them. For months, Relator has sought to have Defendants identify the recipients and custodians of critical documents. For example, on January 19, 2024, Relator told Defendants that with respect to "the metadata issue, a representative

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document (that I mentioned during our call) is Zytiga\_Lit\_05540428 (Landscape Assessment Meeting). The custodian field should reflect all custodians where this document can be found, as well as all recipients in a separate field.” Relator requested Defendants to remedy this deficiency, but months later, Defendants still have not responded with *any* proposals or solutions. Relator notes that this document, which Relator expects will likely play a key role at trial, should have been widely distributed to Defendants’ senior management and key personnel involved in the sales, distribution, and marketing of Zytiga. However, the metadata for the document lists only one custodian and no recipients, and Ms. Kamage denies having ever seen it.

Defendants also say they responded to similar requests years ago, and that these targeted requests are therefore untimely. In this regard, Defendants misleadingly (but repeatedly) state that Relator has failed to press his discovery for “five years.” This is not only false,<sup>2</sup> but it entirely misses the point. Relator reviewed Defendants’ responses and their recent productions, and he has timely served these requests to ensure that important information has been properly identified and produced by Defendants. And beyond doubt, serious gaps in Defendants’ production have been revealed.

One salient example is that for *years*, Defendants did not seem to know with whom their patent prosecution attorneys spoke about the Commercial Success of Zytiga (and instead provided

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<sup>2</sup> Relator notes that because of the motions to dismiss in this case and the antitrust cases, discovery was effectively stayed except for certain ANDA litigation documents until the parties amended and simultaneously exchanged their initial discovery requests on March 25, 2022. And Defendants’ productions throughout 2023 were sporadic, incomplete, and full of gaps, despite diligent efforts by Relator to obtain key documents. The Court may recall that throughout it all, Defendants kept using generic company oppositions as excuses for their spotty productions. Defendants’ accusation therefore is quite puzzling (to be charitable).

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sworn statements that J&J's attorneys spoke with *nobody* at J&J's commercial and marketing departments). Only after Defendants were pressed by Relator to confirm the accuracy of their answers did Defendants finally provide *in November 2023* an updated list of names. Defendants should have known this basic information when they served their initial disclosures in July 2021, and the fact that they operated on grossly incomplete assumptions for so long calls into question the adequacy of their prior productions.

To add to this, Defendants "discovered" on the eve of Ms. Kamage's deposition a trove of documents concerning her and Mr. Tracy's work on the Zytiga "Compound Development Team" and "Clinical Team" that met bi-weekly and discussed many of the factors for the commercial success of Zytiga—including how prednisone coadministration was a significant barrier that had to be mitigated. There were scores of these meetings, complete with agendas and presentations. These meetings were attended not only by Ms. Kamage and Mr. Tracy, but also key personnel at J&J charged with ensuring Zytiga's commercial success (such as Mr. Short). Defendants only produced these documents in January and February 2024—up to a week before Ms. Kamage's deposition on February 15. And during her deposition, Ms. Kamage relied heavily on her supposed discussions at those meetings to justify her belief that she was adequately informed about Zytiga's commercial success. Therefore, among many other things, Requests 68-87 are necessary to reveal what the members of the Compound Development Team and Clinical Teams knew about drivers of Zytiga's commercial success.

Relator also notes that on February 13, 2024, this Court issued an Order permitting fact discovery to be served through February 15, 2024, and extending fact discovery until June 7, 2024.

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(ECF No. 325) Requests 68-78 were served on January 19, 2024. Therefore, there is no basis for Defendants to object that these requests are untimely. As a point of comparison, Relator notes that in *In re: Cathode Ray Tube (CRT) Antitrust Litig.*, No. 4:07-cv-05944-JST (N.D. Cal.), the Court ordered defendant Irico Group in February 2024 to perform additional discovery term searches (ECF No. 6357), despite the case having been filed in 2007. These types of requests for additional search terms, informed by analysis of prior discovery, are an accepted and efficient way for parties to drill down into important topics near the end of fact discovery in complex cases.

*Second*, Defendants say that these requests are overbroad, and they accuse Relator of seeking to overwhelm their resources. Not so. Unlike the typical case, many of the important matters in this case have been litigated at least three times against and by multiple generic companies. As Defendants confirm, nearly six million documents were produced—many from the ANDA Litigation. Relator’s discovery strategy—which was to focus on those documents and then make targeted requests *after* they had been analyzed and strategic gaps identified, is *more efficient* than making blind, shotgun search term requests without the benefit of analyzing a large volume of available documents from related litigation.

*Third*, Defendants say that the requests are not “proportional” to the needs of the case and suggest that Relator can simply ask certain witnesses whether they have seen certain documents instead of having Defendants search their custodial files for the presence of those documents. Defendants’ alternative is plainly insufficient, as the following illustrative example from the deposition of Andrea Kamage confirms.

Ms. Kamage served on a Zytiga commercial leadership committee that she testified was

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“involved in generating” certain critical “long range financial planning” forecasts. (Kamage Tr. at 97) When asked about those long-range financial planning forecasts, Ms. Kamage said she had never seen them before:

Q: Kamage Exhibit 30 is what is seen as LRFP," Long-Range Financial Planning, "2011 NALT," N-A-L-T, "Review Immunology/Oncology" dated March 25th, 2010. And do you understand that "NALT" refers to the North American Leadership Team?

A: I believe it does.

Q: Okay. And have you seen this document before?

A: I don't recognize it.

(Kamage Tr. at 330)

In another document—one of the few that actually specifies Ms. Kamage as a document custodian—Ms. Kamage’s memory wouldn’t permit her to say whether she had ever seen it, and she even denied any memory of having ever opened the email to read the contents. This is why Relator’s targeted document requests are so important, not just for Ms. Kamage, but for all the critical witnesses that Relator has specifically identified:

Q Okay. Now, the first attachment to this email I would have you look at, which is Exhibit 17, and that is a medical presentation, and it's entitled -- so the Bates number of that is 05554482, and the title of the document is "Zytiga Global Medical Affairs." Do you see that?

A. I do.

Q Okay. I would ask you to look at slide 15, and it's entitled, "Mitigate steroid co-dosing requirement for ZYTIGA." Now, have you seen this document before? 0

A I don't recall seeing it before.

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Q. Okay. So you were copied on this email. Did you -- did you open the email and read its contents near the time that it was sent?

A. I don't recall if I did.

(Kamage Tr. at 234-35)

This same email that Ms. Kamage denied ever seeing also included as an attachment an important document known as a SWOT Analysis (Strength, Weakness, Opportunities, Threats) for Zytiga. These SWOT Analyses reveal what Defendants knew about the real reasons for Zytiga's commercial success. Although Ms. Kamage was a recipient of the email—and therefore of the SWOT Analysis—if Relator had to rely solely on her memory alone, there would be no way to tie this important document to Ms. Kamage. This was her testimony, which Defendants suggest to the Court would be an appropriate substitute for the terms and connectors search they claim is unnecessary and duplicative:

Q: Did the global commercial team create or review what's known as SWOT, S-W-O-T, analysis?

A: I don't know.

...

Q: Did you ever see a SWOT analysis for Zytiga?

A: I don't recall.

Q: During the prosecution of the patent?

A: I don't recall.

Q: In your service on the GCT?

A: I don't recall.

Q: And I take it that's the same answer that you don't recall whether you

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saw a SWOT analysis in connection with your work on the compound development team?

A: Correct.

(Kamage Tr. at 92-3)

Clearly, Relator needs to have Ms. Kamage's custodial files searched with additional search terms to confirm her possession and receipt of important documents she now claims to have forgotten. Given that Ms. Kamage's custodial files have previously been gathered by Defendants, searching them for specific terms would not be unduly burdensome. Indeed, saliently missing from Defendants' argument is any attempt to actually specify what they claim is unduly burdensome. Normally, a party claiming undue burden from a terms search provides a "hit report" that quantifies the number of documents that would have to be produced (and which can be de-duplicated automatically through standard document review platforms).

When Relator sought to meet and confer with Defendants about limiting the searches to a more limited set of witnesses, Defendants rejected that idea out of hand, and said they would object to *any* terms and connectors searches, even for indubitably key witnesses such as Ms. Kamage, Mr. Tracy (the other lead prosecuting attorney), Mr. Short (one of the leaders of the Zytiga commercial team), and the other members of the Zytiga Compound Development Team and Global Commercial Team. Searching their custodial files to identify important documents, confirm their receipt, and identify additional documents containing similar key language is of vital importance to ensure that Defendants do not block Relator from obtaining critical evidence. The searches sought are proportional to the needs of this large case, particularly when compared against any (yet unspecified burdens) on a well-resourced company such as Johnson & Johnson and its



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Janssen subsidiaries.

**B. Relator's Document Request No. 65: Personnel Files.**

Request No. 65 (served December 20, 2023) requests personnel files, including resumes, employment history, job descriptions, employer information, and organization charts relating to individuals whom Relator is seeking to depose, or whom Defendants identified as having relevant information. Relator believes that Defendants should be required to produce personnel file documents for the witnesses that it has noticed for deposition (including former employees whom Relator is seeking to subpoena). Such information is necessary for Relator to verify the specific Johnson & Johnson entity for which each witness worked, establish the reporting hierarchy within the relevant corporate entity relating to each witness, and probe those witnesses' credibility. They should therefore be produced. Defendants have only agreed to produce resumes to the extent they exist. That is clearly insufficient, particularly given the many J&J entities that have been sued here. Moreover, resumes may not exist, or they may not precisely identify a particular corporate entity. And organizational charts are important in setting forth reporting structures. Relator is also entitled to test any representation from Defendants concerning a specific entity employer, including determining whether payments for salary or bonuses were made by different legal entities (with any necessary redactions to remove dollar amount or social security numbers, for example).

**C. Relator's Document Request Nos. 61 and 63: Opinions and Articles Drafted by the Patent Attorneys Who Prosecuted the Relevant Patent.**

Request Nos. 61 and 63 (served November 21, 2023) request documents concerning "opinions, articles (published or unpublished, including drafts), and memoranda" drafted by Defendants' patent prosecution attorneys involved in the prosecution of the allegedly fraudulent



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patent concerning inequitable conduct; the duties of patent prosecuting attorneys; patent law issues relevant to this case, such as commercial success; inequitable conduct in patent prosecution; and the False Claims Act.

Defendants say that they will not conduct a search for unpublished articles, opinions, or memoranda. Instead, they have limited their search only to published ones. There is no basis for such a distinction—indeed, Defendants asked for drafts from Relator, and he produced drafts of certain articles as well as numerous non-published confidential memoranda disseminated to private clients. Defendants should be held to their own standard.

### **Defendants' Statement**

For more than five years, this case has languished with little effort on Relator's part to move it forward. This profound lack of diligence has resulted in multiple extensions of the fact discovery period, which would be long closed but for Relator's listlessness. Throughout this litigation, Defendants have responded timely and appropriately to Relator's discovery requests, consistent with their obligations under the Federal Rules. Since 2021, Defendants have produced more than 130,000 documents to Relator consisting of more than 6 million pages. These include documents from the ANDA Litigation, which were produced at *Relator's* insistence in 2021, months before fact discovery opened, *see* ECF 144, as well as documents produced in response to 60 broad and sweeping document requests issued by Relator on March 25, 2022, and May 5, 2023.

Despite Defendants' offers to meet and confer regarding many of those requests, Relator chose to sit on his hands in hopes that Defendants might make his case for him. Defendants have repeatedly advised the Court—and Relator—about this absentee approach. *See, e.g.*, ECF 235 at



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2 (Feb. 21, 2023 Joint Status Report) (discussing Relator’s “lack of diligence” in failing to “even engage with Defendants” regarding their prior document productions); ECF 280 at 3 (July 13, 2023 Joint Status Report) (describing Relator’s “failure to engage . . . on the substance of [Defendants’] production or the objections raised nearly a year earlier”). Yet nothing has changed more than five years into this litigation.

Unable to prove his case through the voluminous number of documents Defendants have produced, and with the close of fact discovery looming, Relator has issued a flurry of duplicative, overbroad, and harassing documents requests. These requests are designed to swamp Defendants with burdensome document gathering and review obligations at the same time as having to address Relator’s 31 deposition demands, while hoping that some heretofore hidden nugget of evidence will materialize. Such demands, in tone and substance, are fundamentally inconsistent with the Federal Rules of Civil Procedure. The events in dispute are already more than a decade old, and Relator filed his complaint more than five years ago. It is past time to move forward to the next phase of discovery. This Court should deny each Request in full.

**A. Relator’s Requests 68 - 87 are Duplicative, Overbroad, and Disproportional to the Need for Discovery Offered by Relator.**

Relator first seeks to compel the production of documents found in the files of 20 custodians from January 1, 2007 to present. Relator offers no reasonable justification for the duplicative nature of these requests, their excessive breadth, or his extreme delay in issuing them.

Moreover, the requests appear purposefully designed to frustrate the reasonable administration of this litigation. Relator issued these requests in close proximity to notifying Defendants—for the first time—in January 2024 that he intended to depose more than 30 witnesses



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before the close of discovery. These broad and sweeping requests—seeking 16 years’ worth of information from 20 witnesses—would require months to fully respond. Yet Relator has insisted that Defendants respond in full within mere weeks or that Relator be entitled to reopen the depositions later on the basis of his late-breaking requests. This is not how discovery is designed to work. Relator had more than two and a half years to request documents in this case. The Court should deny Relator’s attempt to compel responses to these untimely and inappropriate requests for three reasons.

***First, the requests are duplicative.*** Requests 68 – 87 improperly seek to reissue, refine, and relitigate Requests that Relator issued, and that Defendants appropriately responded to, years ago. Relator’s attempt to compel Defendants’ response to these duplicative Requests should be rejected for that reason alone. *See Fed. R. Civ. P. 26(b)(2)(C)(i)* (“[T]he court must limit the frequency or extent of discovery . . . if it determines that: (i) the discovery sought is unreasonably cumulative or duplicative.”). The opening sentence of his Requests readily demonstrates their duplicative nature. Each of Relator’s 20 “new” Requests seeks:

Documents within the custodial files of [custodian] that discuss or analyze Zytiga against any actual or potential competitors, including, without limitation, any factors bearing on the commercial success of Zytiga as described in Paragraphs 84 and 87 of the Second Amended Complaint, or the reasons Zytiga would have to be administered with prednisone or other glucocorticoid, such that any of the following terms are contained within the document as provided in Instruction No. 19

These Requests are wholly duplicative of Requests that Relator has previously issued:

For example, the new Request for documents that discuss or analyze the “commercial success of Zytiga” is duplicative of Relator’s two-year old Request 8, which sought documents

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“concerning the reasons why Zytiga was or was not a commercial success.”<sup>3</sup>

Similarly, the new Requests seek information concerning the “factors” bearing on the commercial success of Zytiga “as described in Paragraphs 84 and 87.” This too has been asked and answered: Relator’s two-year old Request 9 sought documents “tending to support or refute any of the allegations set forth in paragraphs 82, 83, 84 and/or paragraph 87 of the Second Amended Complaint.”<sup>4</sup>

Finally, the new Requests seek documents discussing or analyzing the commercial success of Zytiga that include the “reasons Zytiga would have to be administered with prednisone.” But this is repetitive of what Relator already sought in Request 6,<sup>5</sup> which called for “all documents . . . concerning whether the co-administration of prednisone along with Zytiga is related or not related to the commercial success of Zytiga.”

Defendants responded to each of these past Requests *nearly two years ago*, on April 25, 2022. In those responses, Defendants agreed to meet and confer with Relator to agree upon reasonable and appropriate search parameters (*e.g.*, time period and custodians), and a reasonable

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<sup>3</sup> Relator’s RFP 8 sought: “All documents concerning the reasons why Zytiga was or was not a commercial success for all years before and during prosecution of the ‘438 Patent, including, without limitation, pre-launch studies both before and after January 2010 regarding the prospective and existing commercial success of Zytiga.”

<sup>4</sup> Relator’s RFP 9 sought: “All documents and communications tending to support or refute any of the allegations set forth in paragraphs 82, 83, 84 and/or paragraph 87 of the Second Amended Complaint in this qui tam action, No. 2:19-cv-12107 (ECF No. 63), including all sub-paragraphs.”

<sup>5</sup> Realtor’s RFP 6 sought: “All documents, including communications with your Agents, concerning whether the co-administration of prednisone along with Zytiga is related or not related to the commercial success of Zytiga, regardless of date, or to the commercial success of any inventions embodied within previously pending or allowed claims of the ‘438 Patent.”

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and proportional search protocol, including search terms, to identify material responsive to Relator's Requests. Relator refused to engage with Defendants' offer beyond discussing appropriate date ranges. Instead, Relator demanded that Defendants "move forward with [their] production." Defendants did.

Beginning on September 9, 2022, Defendants produced documents on a rolling basis in response to Relator's first RFPs. Defendants substantially completed those productions five months later, on February 28, 2023, and provided Relator notice of that completion in a letter accompanying their final production. Relator raised no objections and alleged no deficiencies in Defendants' production. Only now—more than a year later—Relator wants a do-over. Realizing that the time for negotiation and challenges to Defendants' productions has long since passed, Relator reissued his old Requests under the guise of new Requests.

Relator's attempts to explain this profound lack of diligence fall flat:

At the outset, he insists that he could not have made these new Requests sooner because they are premised on information he learned from two small, supplemental productions Defendants made in January and February 2024 and could not have learned sooner. *Supra* at 5 (These requests were "possible only after Defendants' prior productions, including key documents that Defendants claim to have only recently found and belatedly produced (in January and February 2024."). That is simply false. Relator issued Requests 68-87 on January 19, 2024 at 6:02 pm ET, *before* either of the two supplemental production were served. (The first production was served at 11:54 pm ET on January 19, 2024 and the second was served on January 20, 2024.) Relator issued these Requests before reading or receiving a single document from the supplemental products; these

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Requests are not in any way related to them.

Separately, he claims complains that Defendants “buried” him in documents. This is nothing more than a blatant attempt to have it both ways. On one hand, Relator argues to the Court that Defendants produced too many documents (to wit—the documents Relator insisted Defendants produce), and, on the other, that Defendants failed to produced enough documents. He cannot have it both ways.<sup>6</sup>

What’s even more troubling: Relator previously assured this Court that he would act with diligence when urging the Court to grant the initial extension of the fact discovery period. *See, e.g.*, ECF 235 at 3. More than a year ago, on February 21, 2023, Relator advised the Court that he would meet and confer with Defendants regarding appropriate “custodians” and “search terms” for their responses to his initial document requests. *Id.* at 2 (stating that he would “meet and confer with Defendants concerning additional custodians . . . as well as appropriate search terms for those custodians.”) He failed to do so.

As Defendants advised this Court at that time, Relator consistently failed to pursue discovery with an appropriate level of diligence. *See id.* (“Relator has not attempted to respond to Defendants’ Responses and Objections—which Defendants provided to Relator on April 25, 2022—or to negotiate with Defendants on the substance of their document production beyond the

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<sup>6</sup> Relator also continues to press the false narrative that Defendants concealed the identify of individuals who were consulted during the patent prosecution until serving revised Interrogatory responses in November 2023. Defendants have addressed this fiction previously. *See* ECF 316 at 14. As Defendants demonstrated there, Relator knew—or reasonably should have known, based on information Defendants had provided to him—the identities of the individuals involved in the prosecution long before that date.

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time period Relator contended was relevant to certain of his RFPs.”). In all the time that has elapsed since then, Relator has still failed to do so. He has now abandoned those initial requests entirely and simply repackaged them as “new” requests. This ruse should be called out for what it is: an attempt for a second bite at discovery as the clock runs out. The Court should reject this attempt.

***Second, the requests are overbroad.*** Requests 68 – 87 are neither “focused” nor “targeted” as Relator claims. These Requests call for the production of 16 years of material (dating back to January 1, 2007). They target the files of 20 different J&J custodians, including the former and current CEOs of Johnson & Johnson. They also target lawyers and paralegals whose files necessarily require an extensive privilege review.

Moreover, although Relator insists he is only targeting “key witnesses,” his discovery demands have more of a “pray and spray” quality. For example, Relator demands documents from two patent paralegals he recently deposed. As both testified in the depositions, their duties in assisting patent prosecuting attorneys were wholly ministerial and they had no substantive knowledge of the facts of this case. Relator accordingly concluded each deposition in less than an hour and a half. Had Relator diligently reviewed the more than 130,000 documents he has already received, he would never have taken these depositions let alone demanded these additional materials.

The belated nature of the Requests makes their overbreadth all the more unreasonable. Although Relator has had Defendants’ documents in his possession for years, Related delayed in issuing these sweeping, duplicative Requests until less than a month and a half before the discovery

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period was set to close (and after prior extensions of the fact discovery period). His motivation for doing so is readily apparent: after failing to prosecute his case for years, Relator hoped that these Requests might offer him a basis for an extension of the discovery period while Defendants produce documents in response to his Requests.<sup>7</sup> Or, in the event fact discovery was not extended, complying with the obligation to search for and review such massive volumes of material would swamp Defendants' legal team at the same time as having to defend against Relator's 31 demanded depositions.

Relator attributes this scattershot approach to his "discovery strategy," which he says necessitated that he first "analyz[e] a large volume of available documents from" the ANDA litigation before he could issue these new, sweeping Requests. This is yet another red herring. Defendants produced all of their own documents from the ANDA litigation to Relator nearly ***two and a half years ago.*** See, e.g., ECF 173.<sup>8</sup> And Defendants substantially completed their

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<sup>7</sup> Tellingly, Relator points to a recent discovery order from a near-20-year-old litigation as the sole authority justifying his duplicative Requests. See *In re: Cathode Ray Tube Antitrust Litig.*, ECF No. 6357, No. 4:07-cv-05944-JST (N.D. Cal. Feb. 20, 2024). This order illustrates Relator's view of how discovery should function—slowly and expensively—which is directly contrary to what Federal Rule of Civil Procedure 1 requires.

<sup>8</sup> Relator complains that Defendants' ANDA litigation productions were "spotty" and "full of gaps." This is not true. Defendant is referring to an issue that frequently has been raised with this Court: In the ANDA litigation, certain documents were produced by generic manufacturer defendants subject to confidentiality restrictions. In this litigation, Defendants produced all of their own ANDA litigation documents to Relator, and then *also* provided documents that were produced to them by the generic manufacturers in the ANDA litigation, *except* for confidential documents for which the generics did not consent. Relator has known about the generics' confidentiality designations for years, and is free to contest those designations with the generics themselves. This issue did not delay Defendants' production of *their own* ANDA litigation documents to Relator, and thus provides no reason why Relator has only now bothered to review



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productions in response to Relator's initial set of forty-four requests for production, many of which are duplicative of these new requests, more than a year ago, on February 28, 2023.

Further, Relator's claim that he needed to review all previously produced documents before he could develop these new requests is not credible. Many of Relator's supposedly crucial search terms are elementary words that are littered throughout his complaint. (*E.g., #9 "Zytiga & (business /s plan)"; #18 "Zytiga & (Overview)"; #3 "prednisone /p (strength weak! obstacle!).*) Relator had all the information he needed to pursue appropriate document discovery in this case long ago; he simply failed to do so, and failed to reasonably engage with Defendants on the extensive and comprehensive document productions that already have been completed in this case.

***Third, these Requests are not “proportional to the needs of the case,” as the Federal Rules require.*** Fed. R. Civ. P. 26(b)(1). According to Relator, each Request is necessary so that he can confirm “whether certain key documents”—*which have already been produced to him*—“reside within the custodial files of important witnesses to establish those witnesses’ knowledge of those facts.” Relator fails adequately to explain why he cannot accomplish this goal through less burdensome means. Most obviously, Relator is free to ask each witness about the documents Relator believes are critical to his case, including whether they have any knowledge or have previously seen the document. This is a far more reasonable and efficient solution to the purported “problem” identified by Relator.

Relator claims this is insufficient, recounting a portion of Ms. Kamage’s deposition, in

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those documents and request additional searches of Defendants’ custodial files. Relator’s lack of diligence is a problem of his own making.

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which Relator presented Ms. Kamage with an email addressed to her and Ms. Kamage replied that she did not recall reading it. According to Relator, this vignette proves that his new search requests are critical to his case. But he fails to articulate why. In the vignette Relator recounts, Defendants had already produced the email at issue; the face of the email lists Ms. Kamage as a recipient. The question whether the email was also stored in her custodial files would do nothing to impact the separate question of whether she remembered it.

According to Relator, Defendants should be compelled to search for, and produce, documents from the files of 20 custodians—which potentially number in the tens of thousands—just so he can confirm whether or not documents already produced to him were located in particular custodians’ files. This is the equivalent of using a sledgehammer to crack open a walnut. Relator has had ample document discovery in this case, and will have ample opportunity to question witnesses about the documents in depositions and at trial. Enough is enough.

Accordingly, this Court should reject Relator’s attempt to compel responses to Requests 68 to 87 in full.

**B. Relator’s Request 65 is a “Classic Fishing Expedition” that this Court Should Reject.**

Relator also asks that this Court compel Defendants to produce personnel files for more than 50 individuals, many of whom Relator does not even intend to depose.<sup>9</sup> This Request is

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<sup>9</sup> Again, Relator fails to provide this Court with his actual Request in an attempt to downplay its overbreadth. Relator’s RFP 65 sought: All resumes; curricula vitae; employment history; descriptions of jobs, duties, and responsibilities; employer information; and organizational charts that relate to or include all individuals (a) identified by Defendants in their (i) Revised Responses to Relator’s First Set of Interrogatories and (ii)) Rule 26(e) Supplemental Disclosures dated March 15, 2023; (b) who testified at trial or deposition for any Defendant in the underlying Patent

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overbroad and readily satisfied by other discovery Defendants offered to provide. As such, the Court should reject it.

As this Court has indicated, broad requests for employment records are an example of a “classic fishing expedition where plaintiff . . . comes before the Court [and] has no concrete proof of anything, but wants to have all-encompassing discovery to see if he can unearth something.” Tr. at 3:20-25, ECF 53, *Holley v. Blue Apron, LLC*, 20-cv-10718 (D.N.J. Jan. 12, 2022) (Kiel, J.). Relator’s Request is just that: it targets records for more than fifty individuals, including outside counsel, experts retained by Defendants in the ANDA litigation, and J&J personnel that Relator has not indicated he wants to depose. Relator similarly cannot articulate what, precisely, he is looking for. According to Relator, these personnel files may have information to help him “probe witnesses’ credibility.” But he does not say what that information is or how it would have any relevance to a witness’s credibility in this particular case. He cannot because he does not know and is merely digging in an attempt to “unearth something.” *Id.* This Court should reject that attempt.

That is especially so because the information sought by Relator is also available through other means. During meet-and-confers, Defendants have agreed to produce a resume for each J&J employee that is deposed to the extent one is kept in the ordinary course. That provides Relator with all the information he purports to need, including the deponent’s employment history,

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Infringement Actions or Inter Partes Reviews; and (c) Julie Baher, Robert Bazemore, Joaquin Duato, Craig Tendler, Mary Todd, Scott White; Matthew Stuckley, Shruti Kusumgar, Silvio Pacheco, Kai Li, Patric Noone, Oly Antonuccio, Vicki Vakiener, Melissa Magee, Matthew Stuckley, S. Shamsi, and Dmitry Gitarts.



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descriptions of jobs, duties, and responsibilities, and their employer information. Moreover, Relator can, and has, sought information about the relationships between J&J's corporate entities through less burdensome means. At the close of fact discovery, Relator propounded Interrogatories seeking information regarding the relationship between J&J's various entities that should resolve Relator's inquiries. And, to the extent any questions remain, Defendants agree to identify the particular J&J entity that employed a particular deponent.<sup>10</sup> Relator is entitled to no more.

**C. Relator's Requests 61 and 63 Seek Material that is Undoubtedly Privileged and Unrelated to the Facts of this Case.**

Relator's Requests 61<sup>11</sup> and 63<sup>12</sup> should also be rejected. These requests seek opinions and

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<sup>10</sup> Relator makes no attempt to address this offer from Defendants.

<sup>11</sup> Relator's RFP 61 seeks: All opinions, articles (published or unpublished, including drafts), and memoranda drafted, co-authored, edited, or reviewed by any prosecuting attorney involved in the prosecution of the '438 Patent and the submission of the '340 and '440 Applications concerning intellectual property issues relevant to this litigation, including, without limitation, any documents that concern, analyze, or refer to (i) inequitable conduct; (ii) the duties of patent prosecuting attorneys, applicants, inventors, and interested parties in connection with patent prosecution; (iii) secondary considerations to traverse obviousness objections to patentability, including, without limitation, surprising results and commercial success; (iv) privilege or work product protection as those doctrines relate to patent prosecution and defending against claims alleging inequitable conduct or patent fraud; (v) obligations or duties of prosecuting attorneys, applicants, inventors, and interested parties involved in patent prosecution to conduct an investigation or due diligence prior to making any submission or representation to the Patent Office or other government agency; (vi) ethical rules or issues relating to patent prosecution, patent litigation, or practice before the Patent Office; (vii) blocking patents and their effect on commercial success arguments in connection with patent prosecution; and (viii) disclosure of information to the government relating to patentability.

<sup>12</sup> Relator's RFP 63 seeks: All opinions, articles (published or unpublished, including drafts), and memoranda concerning the False Claims Act, 31 U.S.C. §§ 3729-33; any state False Claims Act; inequitable conduct in patent prosecution; and the secondary consideration of commercial success in patent prosecution, that were drafted, co-authored, edited, or reviewed by any prosecuting

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memoranda contained in the files of J&J's patent attorneys and issued by J&J legal department from January 1, 2007 to present that relate to a variety of legal topics implicated by this case, including analyses by J&J lawyers about the False Claims Act. In response to Relator's Requests, Defendants have agreed to produce published articles by the attorneys who prosecuted the '438 Patent—Andrea Kamage and Timothy Tracy. Defendants, however, objected to the remaining portions of the Requests as seeking materials that are clearly privileged. It would thus be unduly burdensome and disproportionate to the needs of this case to require Defendants to search for, identify, and review material that would be entirely withheld from production. Once more, these Requests are designed to burden Defendants and, hopefully, troll through Defendants' files hunting for truffles. For those reasons, this Court should reject Relator's attempt to compel production.

Despite the permissive nature of the Federal Rules, discovery in federal court is not limitless. Rule 26 thus permits parties to obtain only “discovery regarding any *nonprivileged* matter.” Thus, courts have refused to compel compliance with broad requests for production where “such discovery would likely heavily involve, if not exclusively involve, privileged material and attorney work-product.” *In re Domestic Drywall Antitrust Litig.*, 2016 WL 4414640, at \*8 (E.D. Pa. Aug. 18, 2016). Here, Relator’s Requests would implicate every aspect of a J&J patent attorney’s legal duties. It would call for Defendants to produce privileged analyses and due diligence relating to every patent that a J&J attorney has prosecuted. It would call for advice and analysis offered in litigations where inequitable conduct was raised as a defense to infringement.

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attorney involved in the prosecution of the '438 Patent and the submission of the '340 and '440 Applications, or otherwise promulgated by Defendants' legal department.

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And it would call for all of J&J's internal analyses regarding every False Claims Act case that it has litigated. Indeed, Relator makes no attempt to explain how these particular Requests would not require Defendants to wade through swaths of privileged information in hopes of finding a handful of nonprivileged documents.

Relator argues that these Requests are commensurate with material that he has been forced to produce. But that argument ignores a critical distinction between Relator and J&J's attorneys: Relator holds himself out as a consultant and offers advice to clients on a non-attorney-client basis; J&J's attorneys do not. As Defendants have previously explained, Relator owns and operates Markman Advisors, a consulting firm that is separate and independent from Relator's law firm. In his consulting capacity, Relator advises clients on a variety of patent related issues. Thus, in seeking to compel Relator's compliance with Defendants' RFPs, Defendants took great care to be exceedingly clear that they were seeking only files maintained in Relator's capacity as a consultant. See ECF 238 at 3-4. In contrast, J&J's patent attorneys do not operate a separate, non-legal business. At all times they act as lawyers acting on behalf of Defendants. Thus, J&J attorneys do not have records containing legal advice that was rendered in a non-legal capacity and not privileged. Any search for information responsive to Relator's Requests would thus require substantial cost and effort to distinguish privileged information from non-privileged, to the extent any such information exists. Relator offers no justification for Defendants bearing that expense and burden, and this Court should reject Relator Requests.<sup>13</sup>

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<sup>13</sup> Relator's representation that he has searched for, and produced, drafts of articles is also dubious. Defendants have identified three documents in Relator's productions (which included little more than 100 documents) that might reasonably be described as "drafts." These documents, however,

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For the aforementioned reasons, this Court should reject each of Relator's requests.

Respectfully yours,

**SILLS CUMMIS & GROSS P.C.**

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are virtually identical to the final articles but for formatting changes made during publication. This necessarily calls into question the propriety of Relator's search for drafts, if any.

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